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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/964,554

09/28/2001

Bruce J. Holub

6580-262

2581

7590

10/25/2002

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 10/25/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,554

Applicant(s)

HOLUB ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-18 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: There is a blank section on page 5. On page 16, Table-1, the numeral 15 appears twice in the second column. One of them should be moved to the top row of the right column. In Tables 2 and 3 some of the entries are not aligned properly. Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Philbrick et al (J Am. Soc. Nephrol., vol. 10, Sept. 1999, pp 85A; mailed to subscribers Aug. 26th, 1999). Philbrick et al disclose the reduction in cyst volumes in mice fed with group B soyasaponins.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for either soyasaponin B_a, B_b or B_c, does not reasonably provide enablement for a combination of any two of the soyasaponins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the

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invention commensurate in scope with these claims. The specification provides examples of treating polycystic kidney disease using only soyasaponin B_b. One of ordinary skill in the art will not be able to extrapolate this to the use of a combination of any two of the soyasaponins for the said treatment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 7 recite, "treating a kidney disease". It is not clear what the disease is. The claim should be restated to include what disease is being treated.

JOINT INVENTORS

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al (WO 99/34916) in combination with Collins et al (WO 99/34810), Shinohara et al (USPN 4217345) and Miyake et al (USPN 4557927).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-18 are drawn to pharmaceutical and nutraceutical compositions for treating a kidney disease comprising soyasaponin B_a, B_b or B_c, and a suitable carrier or diluent; method of isolating soyasaponin B_b via hydrophobic interaction chromatography using a hexadecyltrimethylammonium-substituted Sepharose column from soy molasses as starting sample; using 50-80% ethanol for solubilizing the sample; eluting sample with 80% ethanol and 5% formic acid and a pharmaceutical and nutraceutical sample containing soyasaponin B_b isolated via the said chromatographic method.

Collins et al (WO 99/34916 and WO 99/34810) teach the separation and purification of saponins via hydrophobic interaction chromatography using SP Sephadex hexadecyltrimethylammonium column. The process involves solubilizing the sample in acidified aqueous ethanol, removing polar lipids, acyl glycerides and carotenoids, solubilizing in aqueous alcohol, passing the sample through the column and eluting the sample with acidified aqueous alcohol. Collins also teaches the use of aqueous alcohol, aqueous ethanol (40-80%) in particular (see page 19, line 15 through page 25, line 2 of WO 99/34916 and page 14, line 1 through page 18, line 24). Collins also states that hydrophobic interaction chromatography can be effectively and efficiently carried out on highly substituted anionically and cationically charged polysaccharide gels using any one of a wide variety of counterions (WO 99/34916, page 34, lines 2-5).

However, Collins et al do not teach the isolation of soyasaponin B_b, the use of formic acid and the use of soy molasses as the starting sample in their process. Their process uses soy hull as the starting material and ethanol/water/acetic acid is used initially for extraction. In spite of this difference, it is still possible to use the same process steps for isolating soyasaponin B_b using minor changes like adjusting the percentage of water or alcohol, using formic acid instead of acetic acid or any other acid. A subsequent purification step using preparative liquid chromatography is also a common procedure used in many isolation and purification processes after an initial purification by chromatography.

Shinohara et al teach the use of a pharmaceutical composition containing an effective amount of soyasapogenol and a pharmaceutically acceptable carrier for the treatment of nephritis (see col. 18, lines 1-20).

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Miyake et al teach the use of alpha-glycosyl soyasaponins in sweeteners, chocolate, carbonated beverage and jelly (see cols. 15 and 16, examples 7, 11, 13 and 14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate soyasaponin B_b by using hydrophobic interaction chromatographic column using aqueous acidified ethanol, making pharmaceutical and nutraceutical compositions and using soyasaponin B_a, B_b or B_c, for treating polycystic kidney disease, because all of these are seen to be disclosed in the prior art cited above.

One of ordinary skill in the art would have been motivated to do so because the instant method of isolation via hydrophobic interaction column chromatography lends itself to the separation and purification of a wide range of extractives with similar solubilities in alcoholic solvents and can be effected based on their differential binding to the stationary phase. As a result different fractions of substantially pure soyasaponins in addition to other materials that may be useful as a drug can be isolated from the same source. The hydrophobic interaction column can be anionically and cationically charged and the same column can be regenerated and used several times thereby reducing cost.

Conclusion

1. Claims 1-3 and 5-18 are rejected.
2. Claim 4 is objected to since it depends on a rejected base claim.

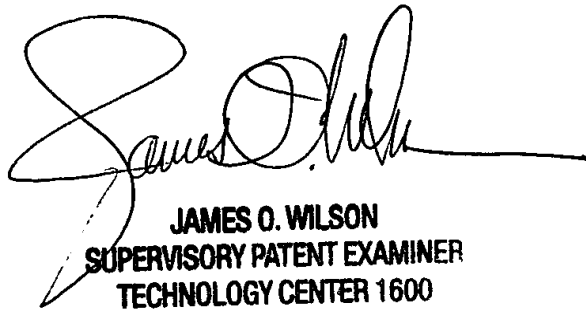
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
October 16, 2002



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600